Attorney Docket No. 018158-011140US Client Ref. No. VX-1073-C1

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Marc Odrich et al.

Application No.: 10/600,027

Filed: June 19, 2003

For: METHOD AND SYSTEMS FOR LASER TREATMENT OF PRESBYOPIA USING OFFSET

**IMAGING** 

Confirmation No. 5696

Examiner: David M. Shay

Art Unit: 3769

APPELLANTS' BRIEF UNDER 37 CFR §41.37

Mail Stop Appeal Brief Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Commissioner:

Further to the Notice of Appeal mailed on November 1, 2010 for the above-referenced application, Appellants submit this Brief on Appeal.

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	REAL PARTY IN INTEREST

#### 1. REAL PARTY IN INTEREST

All right, title, and interest in the subject invention and application are assigned to AMO Manufacturing USA, LLC (formerly VISX, Incorporated), 1700 E St. Andrew Place, Santa Ana, California 92705. As such, AMO Manufacturing USA, LLC a the real party in interest.

#### 2. RELATED APPEALS AND INTERFERENCES

The present application was subject to prior appeal. Per 37 C.F.R. 41.37(c)(1)(x), copies of the following decisions rendered by the Board are included herewith in the Related Proceedings Appendix:

- 1) Decision by the Board of Appeals rendered 5/21/2008
- 2) Decision on Rehearing rendered 10/30/2008

No other appeals or interferences are known which will directly affect, or be directly affected by, or have bearing on the Board's decision in the pending appeal.

## 3. STATUS OF CLAIMS

Claims 1-9, 16 and 17-22 are currently pending and are the subject of this Appeal. Claims 1-9, 16, 17-22 stand rejected under 35 U.S.C. §103(a). No other claims are pending.

#### 4. STATUS OF AMENDMENTS

No amendment to the claims was filed subsequent to the Final Office Action mailed August 4, 2010. A copy of all the pending claims involved in the present appeal is provided in Appendix A attached hereto.

It is noted that a Final Office Action was mailed 5/28/2010, but later withdrawn and replaced with the 8/4/2010 Final Office Action. During a personal interview with the Examiner on 7/20/2010, Applicants' representative pointed out that the 5/28/2010 Office Action was defective as reciting non-existent claims (see Examiner's comparison of claims, pp. 2-3 of

5/28/2010 Office Action). The Examiner agreed to withdraw the 5/28/2010 Office Action, and the 8/4/2010 Final Office Action was issued in replacement.<sup>1</sup>

### 5. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention relates to surgical modifications to the eye. In a specific embodiment, the invention provides ophthalmic surgery techniques which employ a laser to effect ablative photodecomposition of corneal tissue to correct presbyopia and/or other vision defects. U.S. Application No. 10/600,027, filed June 19, 2003 (hereinafter "Application"), page 1, lines 23-26.

Independent claim 1 recites a method of treating a cornea (200) of an eye of a patient to mitigate presbyopia, the eye having a pupil and a cornea (200). The method includes identifying a multifocal ablation shape (211) having a first region (231) providing a near vision correction and a second region (241) providing a far vision correction. An ablation cut profile of the multifocal ablation shape (211) is then adjusted in response to the size of the pupil so as to provide a balance of the near vision correction provided by the first region (231) and the far vision correction provided by the second region (241) for the patient. The method further includes ablating the eye with a series of laser beam pulses according to the adjusted ablation cut profile. These steps are discussed in the Application, for example, at page 5, lines 11-13; page 8, lines 25-30; page 11, lines 16-28; page 13, lines 3-27; page 17, line 20, through page 18, line 10; Figures 1, 2, 3, and 8.

Independent claim 16 recites a method of treating a cornea (200) of an eye of a patient to mitigate presbyopia, the eye having a pupil and a cornea (200). The method includes identifying a multifocal ablation shape (211) having a first region (231) providing a near vision correction and a second region (241) providing a far vision correction. The method further includes adjusting an ablation cut profile for both the first region and the second region of the multifocal ablation shape (211) in response to the size of the pupil so as to provide a balance of

<sup>&</sup>lt;sup>1</sup> In the 5/28/2010 Office Action, the Examiner attempted a comparison between current claim 17 and previous claim 10 (now canceled), but incorrectly represented the language of current claim 17. Withdrawal of the 5/28/2010 Office Action and issuance of the 8/4/2010 Office Action was supposed to correct this error, but the Examiner again

the near vision correction provided by the first region (231) and the far vision correction provided by the second region (241) for the patient. The method further includes ablating the eye with a series of laser beam pulses according to the adjusted ablation cut profile. These steps are discussed in the Application, for example, at page 5, lines 11-13; page 8, lines 25-30; page 11, lines 16-28; page 13, lines 3-27; page 17, line 20, through page 18, line 10; Figures 1, 2, 3, and 8.

Independent claim 17 recites a system for treating a cornea (200) of an eye (30) of a patient to mitigate presbyopia with a multifocal ablation shape (211), the eye (30) having a pupil and a cornea (200). The system includes a laser (28) for making a beam of an ablative light energy (29), a processor (10, 21) in electrical communication with the laser (28), and a tangible medium (12) coupled to the processor (10, 21) and having stored instructions. The stored instruction, if executed by the processor (10, 21), will cause the processor (10, 21) to perform operations including controlling a distribution of a series of laser beam pulses to ablate the multifocal shape (211) on the eye (30), the multifocal ablation shape (211) producing a first region (231) of the cornea providing a near vision correction and a second region (241) of the cornea providing a far vision correction; and determining the distribution of laser beam pulses to ablate the first (231) and second regions (241) of the multifocal ablation shape (211), where the distribution of laser beam pulses for ablating both the first and second regions are determined in response to a signal related to a size of the pupil so as to balance the near vision correction and the far vision correction of the multifocal treatment for the patient. These elements are discussed in the Application, for example, at page 5, lines 11-13; page 8, lines 25-30; page 11, lines 16-28; page 13, lines 3-27; page 13, line 28, to page 14, line 27; page 17, line 20, through page 18, line 10; Figures 1, 2, 3, 4, and 8.

### 6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 1-9, 16 and 17-22 are unpatentable under 35 U.S.C. §103(a) over Frey (US Patent No. 6,027,494) in view of Largent (US Patent No. 6,312,424).

incorrectly represents the language of current claim 17 in the attempted comparison at pp. 3-4 of the 8/4/2010 Office Action.

#### 7. ARGUMENT

Claims 1-9, 16 and 17-22 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Frey in view of Largent. Appellants believe that a case of *prima facie* obviousness cannot be found for at least the reasons set forth below. In particular, the cited references, taken alone or in combination, fail to teach or suggest adjusting *multiple* regions of an ablation profile (as opposed to adjusting *only the outer diameter* of the ablation zone as in Frey) based on an individual patient's pupil size, as this aspect is specifically recited in the current claims.

Furthermore, Appellants respectfully submit that the Examiner's reliance on prior decision by the Board of Appeals is misplaced. The Board previously considered the combination of Frey and Largent during prosecution of the current case. While *different* claims were rejected by the Board, current claims 1-9 were left in condition for allowance.

#### Regarding the Obviousness Rejection over Frey and Largent

Claims 1-9 and 16 have been rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Frey (U.S. 6,027,494) in combination with Largent (U.S. 6,312,424). Claims 17-22 have been similarly rejected under 35 U.S.C. §103(a) as allegedly obvious over Frey in combination with Largent. The rejections are treated together and respectfully traversed.

The determination of obviousness under 35 U.S.C. § 103 is a legal conclusion based on underlying findings of fact. *In re Kotzab*, 217 F.3d 1365, 1369, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000). The underlying factual determinations include: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) where in evidence, so-called secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966). See also *KSR*, 127 S. Ct. at 1734, 82 USPQ2d at 1391. In any instance, *all limitations of the claimed invention must be taught or suggested by the prior art to establish obviousness*. *In re Royka*, 490 F.2d 981, 985, 180 USPQ 580, 583 (CCPA 1974).

## Brief Summary of the Shortcomings of Frey and Largent

Frey and Largent, taken alone or in combination, simply fail to produce the currently claimed invention. Frey is generally directed to a system for determining an *outer diameter* of an ablation zone based on the dilated or dark adapted pupil size so as to address night halos. The purpose of Frey is to ensure that the dark-adapted pupil size does not exceed the ablation zone, so as to preclude night halos. Largent is generally directed to applying a multifocal ablation zone, but Largent does not factor individual pupil size into the ablation. Even when combined, Frey and Largent do not meet every element of Claim 1 because the combination of cited references fail to teach or suggest adjusting *multiple* regions of an ablation profile (as opposed to adjusting *only the outer diameter* of the ablation zone) based on an individual patient's pupil size. Neither reference teaches any relationship between pupil size and inner or multiple regions of an ablation profile. Even if, for arguments sake only, such an adjustment were *attempted* based on the combined references, neither reference provides any guidance adjusting multiple regions of an ablation profile based on pupil size.

#### Detailed Discussion of the Cited References

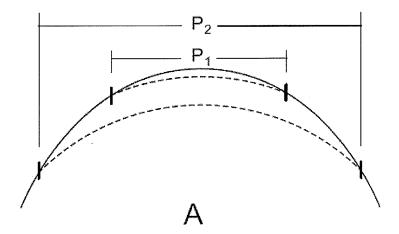
Turning first to Frey, the reference teaches a system for determining the outer diameter of an ablation zone based on the dilated or dark adapted pupil size. The purpose of the system of Frey is to customize the ablation zone diameter to the patient's dark adapted pupil size to eliminate the halo problem arising when the laser-treated corneal region/optical zone is smaller than the dilated pupil diameter (col. 1, lines 40-45; col. 4, lines 23-25). In particular, Frey teaches that the diameter of the optical zone ablated on the cornea is adjusted to "match," or nearly match, the diameter of the dilated pupil (col. 2, lines 57-60).

The concept of optical zone/pupil size matching according to Frey is shown in Illustration  $A^3$ , below. As shown in Illustration A, a pupil with diameter  $P_1$  would have a different ablation diameter than a pupil with diameter  $P_2$  according to the Frey teaching.

<sup>&</sup>lt;sup>2</sup> Appellants submit that at a minimum, the lack of any identified/recognized relationship between inner/multiple ablation regions and pupil size would defeat a rationale for such a proposed modification.

<sup>&</sup>lt;sup>3</sup> Sketch illustrations A-C are not explicitly found in the cited references, but submitted by Appellant in order to visually demonstrate certain differences between the cited art and claimed invention.

Matching an optical zone/ablation shape to different pupil sizes according to Frey simply changes the relative diameter (or outer periphery) and any accompanying change in depth of the ablation zone with respect to P<sub>1</sub> and P<sub>2</sub>, but the ablation profile shape/geometry remains constant (see, e.g., col. 3, lines 20-38; col. 4, lines 10-22).



Largent teaches vision correction via shaping multiple regions of a cornea to provide vision correction at multiple corresponding distances, but does not address pupil size. Rather than a curve as depicted by the dotted lines in Illustration A, above, the multi-focal ablation region taught by Largent includes a central region circumscribed by coaxial annular regions (see, e.g., Figure 2 of Largent, reproduced below).

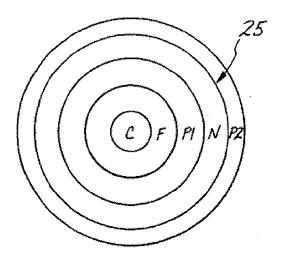
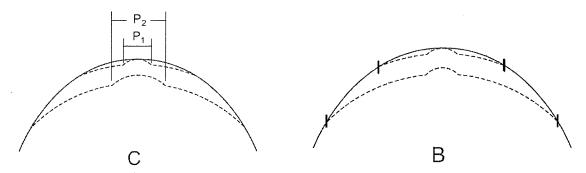


Figure 2 of Largent

As recognized by the Examiner, Largent does not teach measuring pupil size or adjusting any of the ablation zones or annular regions based on a patient's individual pupil size.

Even assuming, for arguments sake only, that Frey and Largent would be combined, Frey would at best simply counsel modifying the *outer diameter* of the Largent multifocal ablation region to "match" the dark-adapted pupil diameter. Nothing can be found in Frey that would direct any modification to the inner ablation regions. Indeed, from the teachings of Frey/Largent there would be no reason to modify the inner regions of the Largent multi-focal ablation region, as altering the inner ablation region shape would do nothing to address the problem of halos due to a dark adapted pupil size extending beyond the overall optical zone - i.e., the problem with which Frey is concerned.

Applying the pupil matching of Frey to the multi-region ablation of Largent, thus, would not teach the method/system of Claims 1, 16, or 17 (depicted below in Illustration C, below, left). In particular, the prior art combination (depicted in Illustration B, below, right) would not involve adjusting or scaling *multiple ablation regions* based on pupil size, in contrast to the claimed methods/systems (shown in Illustration C below, left), in which the ablation shape profile, including inner ablation regions and outer optical zone periphery are adjusted or scaled in response on pupil size.



As shown in the illustration above, the methods/system of Claims 1, 16, 17 differ from the combination of Frey and Largent in a critical way. This difference illustrates a failure of the cited references to teach the claimed invention and, therefore, precludes a finding of *prima facie* obviousness.

Further, it does not appear that combining Frey/Largent to produce the claimed invention would be *technically feasible* without guidance of the present application. Neither reference provides any teachings on *how* adjustments to the multiple regions might be accomplished even if attempted. Neither Frey nor Largent provides any guidance on how to shape an inner ablation region in response to pupil size (or any reason to do so in the first place). Thus, the cited references would be *non-enabling for the modification proposed* by the Examiner.

In contrast to the teachings of the cited references, the present application does provide guidance on *how* to adjust multiple regions based on pupil size. Attention is respectfully drawn, for example, to paragraphs 0026, 0060, 0068-0071 of the published application and corresponding figures. The below listed cut profile equation, for example, is provided in the current specification for shaping multiple regions of a multifocal ablation shape in response to a patient's pupil size:

$$C(r) = (d/\pi) \Sigma i(n_i \theta(r))$$

The specification of the current application provides, inter alia, the following guidance on scaling a multifocal ablation shape in response to dimensions of a patient's pupil:

Preferably, the refractive correction of cut profile C(r) is scaled to match a dimension of the pupil. This scaling may be achieved by appropriately varying the refractive correction entered into the hyperopic lens equation. For example, consider the scaling of an ablation for a 5 mm pupil compared to a 4 mm pupil. If the aspheric surface includes a 1.5D ablated curvature 1.25 mm from the aspheric lens center for the 5 mm pupil, this 1.5D curvature will be ablated 1.0 mm from the aspheric lens center on a 4 mm pupil. This scaling maintains a balance of near and far-vision correction by accommodating individual variability in pupil size. By scaling the cut profile C(r), the scaling of the ablated optical zone is incorporated into the laser treatment table.

These aspects of the claimed invention as recited in claim 1 and described throughout the specification as originally filed, as well as the corresponding advantages in maintaining a more optimal balance of near and far-vision correction by accommodating

individual pupil size variability, are simply not taught in the cited references taken either alone or in any reasonable combination.

In sum, the combination of Frey and Largent does not satisfy the element of Claim 1 of "...adjusting an ablation cut profile of the multifocal ablation shape in response to the size of the pupil so as to provide a balance of the near vision correction provided by the first region and the far vision correction provided by the second region for the patient..." This critical difference between the claimed invention and the prior art precludes a finding of *prima facie* obviousness.

With regard to newly added claim 16, the cited references would at least fail to teach or suggest "...adjusting an ablation cut profile for both the first region and the second region of the multifocal ablation shape in response to the size of the pupil so as to provide a balance of the near vision correction provided by the first region and the far vision correction provided by the second region for the patient..."

Newly added claim 17 will be allowable for at least a similar rationale. The cited references, alone or in combination, at least fail to teach or suggest "...determining the distribution of laser beam pulses to ablate the first and second regions of the multifocal ablation shape, where the distribution of laser beam pulses for ablating both the first and second regions are determined in response to a signal related to a size of the pupil so as to balance the near vision correction and the far vision correction of the multifocal treatment for the patient", as recited in claim 17. Dependent claims 2-9 and 18-22 will be allowable at least for depending from allowable independent claim 1 and 17, respectively, as well as on their own merits.

For at least the above stated reasons, it is respectfully submitted that the current rejections be reversed and the pending claims allowed.

## Regarding the Prior Decisions by the Board of Appeals

As basis for reopening prosecution of the present case and applying the current rejection to claims 1-9 and 16-22, the Examiner relies heavily on the prior decisions by the Board (e.g., Decision by the Board of Appeals rendered 5/21/2008 (hereafter, "Decision by the

Board") and the Decision on Rehearing rendered 10/30/2008 (hereafter, "Decision on Rehearing")). Appellants respectfully submit that neither of those decisions by the Board supports the current rejections of claims 1-9 and 16-22 for at least the following reasons:

- 1) First, while certain <u>different</u> claims (now canceled) were rejected by the Board over Frey/Largent, those claims were drawn to *a different scope of subject matter* and Appellants interpret the Board's decision as being particular to the language of those now canceled claims. Appellants characterization of certain deficiencies in the combined teachings of Frey/Largent, consistent with remarks set forth above, were not disputed previously by the Board. And the currently pending claims more clearly recite aspects not taught by Frey/Largent.
- 2) Second, currently pending claims 1-9 were actually before the Board and open for consideration over Frey/Largent, and the Decisions by the Board left claims 1-9 in *condition for allowance*.

#### Prior Board Decisions and Comparison of Current Claims

By way of background, the cited references to Frey and Largent were addressed at length before the Board on appeal. The Board affirmed the rejection of prior claims 10-15 (now canceled) under 35 U.S.C. 103(a) in view of Frey/Largent, but did <u>not</u> extend the same obviousness rejection to current claims 1-9. Appellants believe the Board's prior rejection over Frey/Largent was intended to be limited prior claims 10-15, rather than extending to the *different claims* currently pending. A comparison of the currently pending independent claims 1, 16 and 17 to prior claim 10 (previously rejected by the Board and now canceled) is a good place to start.

First is a comparison of prior claim 10 (now canceled) and current claim 17. In the 5/28/2010 Office Action (pp. 2-3) and again in the 8/4/2010 Final Office Action (pp. 3-4), the Examiner attempted to present comparison of prior claim 10 (now canceled) and current claim 17. In both instances, the Examiner incorrectly represented the language of current claim 17.<sup>4</sup> An accurate comparison of these claims is presented below, with different language of claim 17 emphasized in bolded/underlined text:

Prior Claim 10 (now canceled)

Current claim 17 (currently pending)

<sup>&</sup>lt;sup>4</sup> As indicated above, the 5/28/2010 was withdrawn as being defective for incorrectly listing a non-existent claim 17. The 8/4/2010 Final Office Action was re-issued to correct this error, but again incorrectly listed currently pending claim 17.

- 10. A system for treating a comea of an eye of a patient to mitigate presbyopia with a multifocal ablation shape, the eye having a pupil and a comea, the system comprising:
- a laser for making a beam of an ablative light energy;
- a processor in electrical communication with the laser; and

a tangible medium coupled to the processor and having stored instructions that, if executed by the processor, will cause the processor to perform operations comprising:

controlling a distribution of a series of laser beam pulses to ablate the multifocal shape on the eye, the multifocal ablation shape producing a first region of the cornea providing a near vision correction and a second region of the cornea providing a far vision correction; and

determining the distribution of laser beam pulses to ablate the first and second regions of the multifocal ablation shape, where the distribution is determined in response to a signal related to a size of the pupil so as to balance the near vision correction and the far vision correction of the multifocal treatment for the patient.

- 17. A system for treating a cornea of an eye of a patient to mitigate presbyopia with a multifocal ablation shape, the eye having a pupil and a cornea, the system comprising:
- a laser for making a beam of an ablative light energy;
- a processor in electrical communication with the laser; and

a tangible medium coupled to the processor and having stored instructions that, if executed by the processor, will cause the processor to perform operations comprising:

controlling a distribution of a series of laser beam pulses to ablate the multifocal shape on the eye, the multifocal ablation shape producing a first region of the cornea providing a near vision correction and a second region of the cornea providing a far vision correction; and

determining the distribution of laser beam pulses to ablate the first and second regions of the multifocal ablation shape, where the distribution of laser beam pulses for ablating both the first and second regions are determined in response to a signal related to a size of the pupil so as to balance the near vision correction and the far vision correction of the multifocal treatment for the patient.

Claim 1, previously considered by the Board but left in condition for allowance, includes language *not found in prior claim 10* (now canceled). Current claim 1 is believed distinguished from Frey/Largent and directed to a different scope of subject matter compared to prior claim 10 (now canceled). In particular, claim 1 recites "...adjusting an ablation cut profile of the multifocal ablation shape in response to the size of the pupil so as to provide a balance of the near vision correction provided by the first region and the far vision correction provided by the second region for the patient...", which is not found in prior claim 10 (now canceled).

A comparison of currently pending claims 1 and 16 is listed below. Claim 16 is similar to claim 1, but even more explicitly recites that *both* the first and second regions of the cut profile are adjusted in response to pupil size. The below comparison illustrates additional language in claim 16 compared to claim 1.

### Claim 1 (currently pending)

1. A method of treating a cornea of an eye of a patient to mitigate presbyopia, the eye having a pupil and a cornea, the method comprising:

identifying a multifocal ablation shape having a first region providing a near vision correction and a second region providing a far vision correction;

adjusting an ablation cut profile of the multifocal ablation shape in response to the size of the pupil so as to provide a balance of the near vision correction provided by the first region and the far vision correction provided by the second region for the patient;

ablating the eye with a series of laser beam pulses according to the adjusted ablation cut profile.

## Claim 16 (currently pending)

16. A method of treating a cornea of an eye of a patient to mitigate presbyopia, the eye having a pupil and a cornea, the method comprising:

identifying a multifocal ablation shape having a first region providing a near vision correction and a second region providing a far vision correction;

adjusting an ablation cut profile <u>for both</u> the first region and the second region of the multifocal ablation shape in response to the size of the pupil so as to provide a balance of the near vision correction provided by the first region and the far vision correction provided by the second region for the patient;

ablating the eye with a series of laser beam pulses according to the adjusted ablation cut profile.

## Examiner's Reopening of Prosecution and the Current Rejections

When current claims 1-9 were previously before the Board, the Examiner's rejection of those claims under 35 U.S.C. 112, first paragraph, was reversed pursuant to the Decision by the Board and the Decision on Rehearing, thereby placing claims 1-9 in condition for allowance. Rather than permitting claims 1-9 to proceed to allowance, the 11/12/2009 Office action reopened prosecution and applied the previously addressed combination of Frey and

Largent to current claims 1-9. The 8/4/2010 Final Office Action relies heavily on the prior Board Decisions to support the alleged obviousness of claims 1-9, 16-22.<sup>5</sup>

The rationale for reopening prosecution and applying the current obviousness rejection, as stated in the 11/12/2009 Office action, was that the Board's affirmation of written description support for claims 1-9 "enlightened the examiner" as to the scope of subject matter of those claims, and, as a result of the Board's broad construction, those claims "are now open to an obviousness inquiry." (page 2, 4 of 11/12/09 Office action).

Appellants respectfully disagree with this rationale, since originally filed claims 1-9 have been open to obviousness inquiry throughout prosecution, and the scope of those claims is unaltered by the Board's decisions. In reversing that rejection, the Board affirmed the presence of such written description support, but raised no new issues with respect to claim construction or scope of subject matter embraced by those claims.

Additionally, the issue of obviousness now being re-visited is believed to have already been considered with respect to current claims 1-9. It is well established that a challenge to written description support does not preclude examination of claim patentability under other statutory provisions, including 35 U.S.C. §103.<sup>6</sup> Thus, the originally filed claims 1-9 have been open to an obviousness inquiry throughout prosecution, and those claims presumably were already thoroughly evaluated for obviousness in view of Frey/Largent since those references were considered by the Examiner at least since July 2005 (see, e.g., Office action mailed 7/25/2005).

Moreover, it is believed that the issue of potential obviousness of claims 1-9 in view of Frey and Largent has already been considered by the Board. Per MPEP§1213.02 and 37 CFR 41.50, and in further view of the written description guidelines discussed above, the Board has express authority during appeal to make a rejection of any of the claims pending in the case at hand, including rejection on either the same or on different grounds from those applied by the

<sup>&</sup>lt;sup>5</sup> Four pages of 8/4/2010 Final Office Action (pp. 5-9) are devoted to quoting the Board's prior Decision on Appeal, but the Examiner ignores the fact that claims 1-9 were left in a condition for allowance per that Decision.

<sup>&</sup>lt;sup>6</sup> The USPTO's written description guidelines explicitly instruct that, "[r]egardless of the outcome of [a written description determination], Office personnel <u>must</u> complete the patentability determination under all relevant statutory provisions of title 35 of the U.S. Code", including 35 U.S.C. §103 (MPEP §2163(III), emphasis added).

Examiner. In the present case, the issue of obviousness over Frey/Largent of <u>any</u> of the pending claims, including current claims 1-9, was squarely before the Board both in forming the initial decision and during reconsideration. In both instances, the Board declined to reject claims 1-9 over Frey/Largent, even though the issue of obviousness in view of those references was being considered by the Board.

Appellants further submit that the Board's affirming of the obviousness rejection of prior claim 10 (now canceled) over Frey/Largent does <u>not</u> necessarily support a corresponding rejection to the *differently defined* invention of claims 1-9 or 16-22, as alleged in the current Office action. The Board's decision regarding obviousness in view of Frey/Largent was *expressly specific to the language of claim 10*<sup>7</sup>. Thus, the Board's rationale for affirming rejection of prior claim 10 does not apply to current independent claims 1, 16 or 17, which recite different language and, therefore, includes a differently defined scope of subject matter. As such, the Board's conclusion of obviousness over Frey/Largent does not extend beyond the specific language of prior claim 10 in the manner suggested by the Examiner.

Moreover, neither the Decision by the Board nor the Decision on Rehearing contradicts Appellants position, as stated herein and previously made of record, regarding the failure of Frey and/or Largent to teach adjusting multiple regions of a multifocal ablation shape in response to size of a patient's pupil. For example, in the Request for Rehearing filed 7/21/2008 (see, e.g., pages 3-9, 13), Appellants noted that the proposed combination of Frey/Largent might at best direct a skilled artisan to adjust the outer periphery of a multi-region ablation shape of Largent and any accompanying change in ablation depth, but would not direct any adjustment to an inner ablation region. In affirming the rejection of claim 10, the Board reasoned simply that "[c]laim 10 does not recite 'adjusting the inner ablation regions'" (Decision on Rehearing, p. 7). Thus, the Decisions by the Board might indicate that claim 10 did not sufficiently recite those elements Appellants identified as missing from the prior art of Frey and

<sup>&</sup>lt;sup>7</sup> See, e.g., Decision on Rehearing, page 3, addressing the scope and content of Frey/Largent "...in the manner recited in claim 10" and "vis-à-vis claim 10"; Decision on Rehearing, page 5, stating "...in can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed invention does..." (original emphasis); Decision on Rehearing, page 5, stating "...whether there

Largent. The Board, however, did not dispute Appellants characterization of those references as failing to teach adjusting multiple regions of a multifocal ablation shape in response to size of a patient's pupil – a distinction more clearly recited in the currently pending claims.

Thus, neither the Decision by the Board nor the Decision on Rehearing supports the current rejection of claims 1-9, 16-22 as obvious in view of Frey and Largent as stated in the current Office action. Accordingly, Appellants respectfully request that the rejections of claims 1-9, 16-22 under 35 U.S.C. 103(a) be withdrawn.

## 8. CONCLUSION

For these reasons, it is respectfully submitted that the rejection should be reversed.

Respectfully submitted,

Dated: 12 30 7010

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### 9. CLAIMS APPENDIX

1. (Original) A method of treating a cornea of an eye of a patient to mitigate presbyopia, the eye having a pupil and a cornea, the method comprising:

identifying a multifocal ablation shape having a first region providing a near vision correction and a second region providing a far vision correction;

adjusting an ablation cut profile of the multifocal ablation shape in response to the size of the pupil so as to provide a balance of the near vision correction provided by the first region and the far vision correction provided by the second region for the patient;

ablating the eye with a series of laser beam pulses according to the adjusted ablation cut profile.

- 2. (Original) The method of claim 1, wherein the ablation cut profile further comprises a third region providing an intermediate optical surface having an optical power continuously varying between the first region providing near vision correction and the second region providing far vision correction, so as to provide intermediate vision correction with the intermediate optical surface.
- 3. (Original) The method of claim 2, wherein the intermediate optical surface varies from a first optical power near the first region to a second optical power near the second region.
- 4. (Original) The method of claim 3, wherein the difference in optical power between the first optical power near the first region and the second optical power near the second region has a range from about 1 to 4 D.
- 5. (Original) The method of claim 1, wherein the first region is disposed centrally in relation to the pupil of the eye.
- 6. (Original) The method of claim 1, further comprising scaling the ablation cut profile in relation to the size of the pupil.

- 7. (Original) The method of claim 6, wherein the step of scaling of the ablation cut profile is done so as to scale the optical power of the ablation cut profile in relation to the size of the pupil.
- 8. (Original) The method of claim 7, wherein the optical power of the first region remains constant during the step of scaling.
- 9. (Original) The method of claim 7, wherein the optical power of the second region remains constant during the step of scaling.
  - 10-15. (Canceled).
- 16. (Previously Presented) A method of treating a cornea of an eye of a patient to mitigate presbyopia, the eye having a pupil and a cornea, the method comprising: identifying a multifocal ablation shape having a first region providing a near

vision correction and a second region providing a far vision correction;

adjusting an ablation cut profile for both the first region and the second region of the multifocal ablation shape in response to the size of the pupil so as to provide a balance of the near vision correction provided by the first region and the far vision correction provided by the second region for the patient;

ablating the eye with a series of laser beam pulses according to the adjusted ablation cut profile.

- 17. (Previously Presented) A system for treating a cornea of an eye of a patient to mitigate presbyopia with a multifocal ablation shape, the eye having a pupil and a cornea, the system comprising:
  - a laser for making a beam of an ablative light energy;
  - a processor in electrical communication with the laser; and
- a tangible medium coupled to the processor and having stored instructions that, if executed by the processor, will cause the processor to perform operations comprising:

controlling a distribution of a series of laser beam pulses to ablate the multifocal shape on the eye, the multifocal ablation shape producing a first region of the cornea providing a near vision correction and a second region of the cornea providing a far vision correction; and

determining the distribution of laser beam pulses to ablate the first and second regions of the multifocal ablation shape, where the distribution of laser beam pulses for ablating both the first and second regions are determined in response to a signal related to a size of the pupil so as to balance the near vision correction and the far vision correction of the multifocal treatment for the patient.

- 18. (Previously Presented) The system of claim 17, wherein the first region providing near vision correction is disposed centrally in relation to the pupil of the eye.
- 19. (Previously Presented) The system of claim 17, wherein the near vision correction and the far vision correction are balanced with a variable of a refractive correction in response to the size of the pupil.
- 20. (Previously Presented) The system of claim 19, wherein the variable of the refractive correction includes a dimension across the refractive correction.
- 21. (Previously Presented) The system of claim 17, wherein the near vision correction and the far vision correction are balanced in response to the size of the pupil so as to scale a dimension across the first region providing near vision correction in relation to the size of the pupil.
- 22. (Previously Presented) The system of claim 17, wherein the near vision correction and the far vision correction are balanced in response to the size of the pupil so as to scale a dimension across the second region providing far vision correction in relation to the size of the pupil.

 $\frac{PATENT}{Attorney\ Docket\ No.\ 018158\text{-}011140US}$ 

# 10. EVIDENCE APPENDIX

None.

## 11. RELATED PROCEEDINGS APPENDIX

Copies of the following Decisions by the Board are attached herewith:

1) Decision by the Board of Appeals rendered 5/21/2008 (US Appl. No.

10/600,027).

2) Decision on Rehearing rendered 10/30/2008 (US Appl. No. 10/600,027).